

# The Feasibility of a Community-Based Directly Administered Antiretroviral Therapy Program

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**Improved treatment-adherence support programs are needed to help human immunodeficiency virus (HIV)–infected persons comply with complex highly active antiretroviral treatment (HAART) regimens. In an experimental directly administered antiretroviral therapy (DAART) program, treatment-naïve and treatment-experienced persons who experienced failure of no more than 1 prior regimen were recruited from 3 public HIV/AIDS clinics in Los Angeles County. For 6 months, trained community workers observed ingestion of 1 of 2 daily HAART doses, 5 days per week, and questioned the patient about the second dose, which enabled intense adherence monitoring and real-time intervention. From November 2001 through November 2003, there were 67 DAART patients enrolled (69% Latino, 21% African American, and 9% white; 63% with annual income of <\$10,000). Preliminary findings show that a DAART program based in 3 public HIV/AIDS clinics was feasible in a low-income urban population. Effective communication between the DAART staff, the medical providers, and the pharmacy is essential for the successful implementation of this program.**

Although HAART has resulted in tremendous improvement in the disease course for many HIV-infected persons [1], optimal adherence to the complex treatment regimens is difficult for many [2, 3]. Data suggest that  $\geq 95\%$  adherence to antiretroviral therapy is needed for effective virus suppression [4–6]. The most common reason cited for lack of virus suppression among HIV-infected persons who experience failure of multiple HAART regimens has been poor adherence to treat-

ment [7]. Poor adherence can lead to not only incomplete virus suppression but also the development of drug-resistant strains of HIV, resulting in an unfavorable disease course [7–12]. Several investigations of a variety of populations have found a range of nonadherence to HAART, from 11% to 62% [8, 11, 13–15]. In persons with adequate adherence, there was an improvement in disease course and suppression of virus loads [3, 5, 11, 13].

Recently, several models of treatment-adherence support have emerged in response to the recognition of the difficulties in sustaining lifelong adherence to the complex treatment regimens. Two major adherence support models that have arisen are directly observed HAART, in which trained personnel observe the ingestion of  $\geq 1$  daily HAART doses, and case management, in which patients meet regularly with a case manager to discuss adherence issues [6, 16–21]. Here we present early experience from a directly administered antiretroviral therapy program (DAART) in which HAART medications are dispensed in-person in the community by dose.

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## METHODS

**Study design.** The DAART program is 1 arm of a 3-arm randomized trial of adherence support for HAART for HIV-infected persons. The larger trial involves the recruitment of 300 HIV-infected patients from 3 large public HIV/AIDS clinics in Los Angeles County, one of the largest and most ethnically diverse counties in the United States [22]. Patients are stratified by clinic and HAART experience (i.e., treatment naive or treatment experienced) to ensure even distribution of naive and experienced patients across the 3 study arms at the 3 clinics. The program has no role in determining or influencing whether the patient decides to initiate or change a HAART regimen, because this is determined by the patient and the health-care provider before study recruitment.

Participants were randomized to receive DAART, a clinic-based intensive adherence case-management model, or standard of care at the clinic. DAART participants receive daily delivery and observation of ingestion of 1 dose of HAART medications by a specially trained community worker, 5 days per week. Patients participating in the case management program meet weekly with a trained case manager to overcome barriers to HAART adherence. Standard care patients receive adherence support according to the practice in the clinics, which includes education by the providers and typical follow-up on adherence issues. The primary end point for the study of virus suppression at 6 months will be available in 2004.

**Study setting.** It is estimated that >50,000 persons in Los Angeles County are living with diagnosed and undiagnosed HIV infection or AIDS [23]. The HIV epidemic in Los Angeles County is largely driven by sexual exposure: 66% of men who received a diagnosis of AIDS in 2001 were men who have sex with men or who are also injection drug users, and 29% of women who received a diagnosis of AIDS in 2001 were exposed to HIV heterosexually [24]. Among the total number of persons who received a diagnosis of AIDS in 2001 in Los Angeles County, 72% were persons of color (44% Latino and 25% African American). Patients are recruited from 3 public HIV/AIDS clinics in Los Angeles County that are located in the geographic areas with some of the highest rates of persons living with AIDS in the county.

**Patient inclusion criteria for the study.** Patients eligible for inclusion are persons  $\geq 18$  years of age with a history of failure of no more than 1 HAART regimen or prescription of a first HAART regimen within the previous 6 months. The rationale for including patients in the study who have not received multiple regimens is that these persons are less likely to be infected with drug-resistant virus strains and are most likely to achieve virus suppression if their adherence is optimal. However, the procedures described below for DAART should be equally feasible for patients with more treatment experience.

Additional eligibility criteria are that a patient's HAART reg-

imen is taken no more than twice daily and that a patient lives or works within the Metropolitan or South Service Planning Areas of Los Angeles County. These latter criteria are necessary for study staff to conduct daily visits to patients within a defined area of Los Angeles County. In addition, consistency among participants in the number of daily HAART doses is necessary for the uniform administration and evaluation of the DAART program. Eligible participants must also speak English or Spanish to effectively communicate with study staff. Table 1 shows that 69% of the DAART patients recruited from the clinics are Latino, 61% are Spanish speaking, and the majority are male (76%). The demographic characteristics of the study group are similar to those of the clinic populations. At baseline or time of entry into the DAART program, 90% of participants were taking twice-daily HAART regimens.

Appropriate informed consent was obtained, and clinical research was conducted in accordance with guidelines for human

**Table 1. Characteristics of patients in a directly administered antiretroviral therapy program in Los Angeles County, California, 2001–2003.**

Characteristic	No. (%) of subjects (n = 67)
Sex	
Male	51 (76.1)
Female	15 (22.4)
Transgender (M to F)	1 (1.5)
Race or ethnicity	
Latino	46 (68.7)
African American	14 (20.9)
White	6 (9.0)
Other	1 (1.5)
Age, years	
20–29	16 (23.9)
30–39	23 (34.3)
40–49	22 (32.8)
$\geq 50$	6 (9.0)
Foreign born	45 (67.2)
Spanish speaker	41 (61.2)
Annual income <\$10,000	42 (62.7)
Drug use in past 30 days	
Injection	7 (10.4)
Injection and noninjection	16
Years since HIV diagnosis, mean (range)	4.9 (0.4–21.5)
Treatment experience	
Naive	26 (38.8)
Experienced	41 (61.2)
Regimen type	
Once- daily HAART	7 (10.4)
Twice-daily HAART	60 (89.6)

**Table 2. Elements of a directly administered antiretroviral therapy program among a low-income urban population in Los Angeles County, California, 2001–2003.**

Element	Description
1	Daily visits by a trained community worker 5 days per week for 6 months
2	Direct observation of 1 of 2 daily HAART doses by the trained community worker
3	The patient and the community worker meet daily at an agreed-upon location (could include home, work, school, restaurant, or shelter)
4	On Fridays and holidays, the community worker gives the patient weekend and holiday doses for later self-administration
5	Patient is given a 7-day supply of HAART medications to keep at home in the event a meeting with the community worker is missed

experimentation as specified by the US Department of Health and Human Services, the Los Angeles County Department of Health Services, the University of Southern California (UCLA) Medical Center, and the Harbor-UCLA Medical Center.

**The DAART model.** The DAART model consists of a trained community worker directly observing a patient ingest 1 of 2 daily doses of HAART, 5 days per week, for 6 months (table 2). The current program is staffed with 3 community workers who manage a maximum of 10 patients each at any given time. The client and the community worker agree on a location and time at which to conduct the daily meetings. At the time of the daily meeting, the community worker observes the ingestion of 1 HAART dose and delivers the other daily dose for later self-administration. Typically, the DAART patients have elected that the community worker observe the ingestion of their morning dose rather than their evening dose, although either option is available to each patient. The community worker returns the following day at the same time, asks the patient whether they took their second dose on the previous day, records the patient's response, and collects the packaging from the previous day's evening dose. On Fridays and holidays, the community worker gives the patient their weekend and holiday doses for later self-administration. The meetings between the community worker and the patient typically occur at a patient's home, although meetings also take place at a patient's work location or school, restaurants, or shelters. Patients are given a 7-day supply of their HAART medications to keep at home in the event that a meeting with the community worker is missed.

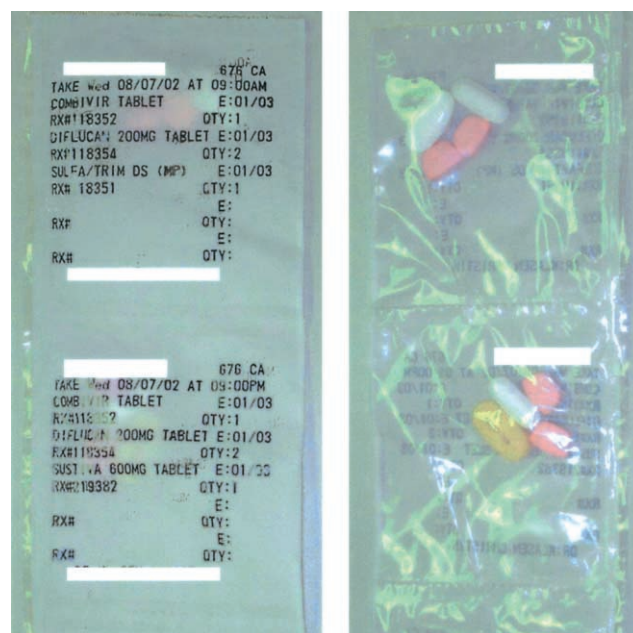
After 6 months of DAART, patients are given the option to move to a less intense intervention, in which they meet weekly with a clinic-based case manager to discuss adherence issues and receive social support referrals. The rationale for moving patients to a less intense intervention is to give patients the

time and resources necessary to manage adherence independently after the intense daily contact of the DAART program.

**Packaging of individual daily doses.** All of the unit doses that are delivered to patients who participate in the DAART arm are packaged specially by a private local pharmacy. The pharmacy packages the individual doses in small, sealed plastic bags that are clearly labeled (figure 1). The packaged medications are delivered to the study headquarters by the pharmacy and kept in a central location that is locked, with access limited to study staff. The pharmacy conducts a monthly inspection of the refrigerator and cabinets that house the medications at the study site to ensure proper storage.

The private pharmacy does not add an additional charge to package and deliver the medications, although the pharmacy does acquire more business through their affiliation with the DAART program and may retain patients following completion of the program. In the current program, 3 pharmacies have been used because of management changes and changes in the AIDS Drug Assistance Program that have resulted in reduced reimbursement for HIV medications, causing some pharmacies to discontinue their HIV medication programs.

**Evaluation of symptoms and side effects and communication with health-care providers.** When the daily DAART visits begin, the community worker reviews a checklist of symptoms of disease and medication side effects with each patient. Symptoms and side effects are assessed daily for the first 2 weeks of the program and weekly thereafter. Patient symptoms, side effects, and missed HAART doses are typically reported



**Figure 1.** Unit dose packaging and labeling of HAART for patients in a directly observed antiretroviral treatment program, Los Angeles, California, 2001–2003.

by the community worker to a patient's health-care providers within 24 h.

**Staff training.** An physician experienced with HIV infection provided training to the community workers regarding antiretroviral drugs, background on the structure of antiretroviral regimens, the goals of therapy, signs and symptoms of potential clinical events, and the side effects of HAART medications. A licensed clinical social worker provided training to the community workers on leading a patient through a self-assessment to identify problems that need to be reported to the clinic staff, observation and documentation of a patient's ingestion of HAART drugs, developing skills to effectively communicate problems with DAART to the patient's providers, establishing appropriate professional boundaries, and awareness of the cultural sensitivity related to HIV infection. The community workers also participated in a local community-based organization's treatment advocacy training. In addition, staff are trained in procedures for handling and reporting adverse events such as suicide attempts and hospitalizations.

## RESULTS AND DISCUSSION

**Acceptability of DAART by patients.** Concerns have been raised that a DAART program may stigmatize patients and not be acceptable to HIV-infected persons. No patients have dropped out of the DAART arm because they felt stigmatized by the visits. In addition, exit surveys of patients who have completed 6 months of DAART are generally favorable. Many DAART patients have developed a positive rapport with their community worker, whom they have grown to trust and accept as a health worker who is having a positive effect on their lives.

**Limitations.** Patients who are treatment naive or have experienced failure of no more than 1 HAART regimen were included in this intervention, because the major study outcome, virus load response, was expected to be comparable in these 2 groups. However, the results cannot be generalized to patients who have experienced failure of multiple regimens, although it is expected that the DAART intervention could also be effective in this group.

**Recommendations.** There are certain key factors to the successful implementation of a DAART program (table 3). Reliable contact information must be available for the community worker in the event that a patient needs to reach them to change the location or time of the meeting. For this reason, a reliable cellular telephone is an essential tool for a community worker, who is likely to be in the field conducting patient visits when another patient may need to contact him or her. It is also important that the community worker's schedule be flexible, to allow unusual hours, such as a split shift, in which the community worker may work for several hours in the morning conducting patient visits, have time off during the day, and

**Table 3. Recommended key components of a successful directly administered antiretroviral therapy (DAART) program in a low-income urban population.**

Component	Description
1	Flexibility in work schedule for community workers
2	Effective communication between DAART program staff and the patient's health-care providers
3	Effective communication between DAART program staff and the pharmacy that conducts the unit dose packaging.
4	Capacity to refer patients to needed social support services
5	Integration of DAART program staff with HIV/AIDS clinic staff

resume work hours in the evening to accommodate evening patient visits. An alternative is to structure staffing so that certain community workers work an early morning shift to conduct morning patient visits and other staff work afternoon and evening shifts to conduct evening patient visits. It is also critical that community workers be fluent in the language that their patients speak.

Early experience has also shown that ~70% of the DAART patients have psychosocial needs beyond the skills and resources of a community worker and have requested referrals for additional social support services. Although patients can be referred to existing case management services at the clinic, future DAART programs among similar low-income urban populations should consider establishing a mechanism to provide referrals for social support services, such as housing, nutrition support, mental health referrals, and legal support.

In addition, it is essential that communication between the DAART staff and the pharmacy be optimal. Delivery of medications must be timely to ensure that the community worker can get a patient his or her needed medications at their correct dosing time. One recommendation is to enter into a monetary contract that would make the pharmacy accountable to the DAART program.

Close coordination and effective communication between the community workers, other DAART program staff, and a patient's medical providers is essential for the effective conduct of this program. This can be accomplished through participation of community workers in patient case conferences or medical staff meetings or through provision by the community worker of detailed patient notes in the medical chart that updates health-care providers on a patient's participation in the DAART program. A clinic-based DAART program will also be most effective if the staff can be integrated with existing clinic staff to maximize coordination and oversight of patient care and services.

## CONCLUSION

Early experience with a DAART program based in 3 public HIV/AIDS clinics has shown that this program is feasible in a low-income, urban population. The results of the primary end point of the study will provide useful data on the relative benefits of a DAART model compared to standard of care.

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